

REMARKS

Claims 4-15, 18-23, 39-47, and 49-56 are presently pending in the case. Claims 4-15, 18-23, 39-47, and 49-51 have been amended. Claims 52-56 have been added. The amendments and new claims are supported by the specification and claims as originally filed.

Reconsideration of the present case in view of the above amendments and the remarks herein is requested.

Claim rejections under 35 USC 112

The Examiner rejected claim 43 under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. The Examiner's objection to the language in claim 43 is believed to be overcome by the above amendment.

Claim rejections under 35 USC 103(a)

The Examiner rejected claims 4, 8-15, 18-23, 39-47, and 49-50 under 35 USC 103(a) as being unpatentable over U.S. Patent 5,855,913 to Hanes et al (hereinafter Hanes et al) in view of U.S. Patent 5,149,543 to Cohen et al (hereinafter Cohen et al) and further in view of U.S. Patent 5,308,620 to Yen (hereinafter Yen). The rejection is traversed.

Independent claim 39, for example, is not rendered unpatentable by Hanes et al. Claim 39 is to an inhaleable powder composition comprising a plurality of particulate microstructures, said microstructures comprising a structural matrix comprising an active agent, calcium and a phospholipid, wherein said microstructures have, inter alia, a mean geometric diameter of 1-30 microns. Hanes et al does not disclose or suggest a particular microstructure comprising calcium. Therefore, Hanes et al does not render claim 39 unpatentable.

Furthermore, Hanes et al and Cohen et al do not render claim 39 unpatentable. Hanes et al discloses aerodynamically light particles comprising a drug and a surfactant and optionally comprising a polymer, such as poly(lactic acid) or poly(glycolic acid). Cohen teaches the use of a multivalent polyion, such as calcium, to cross-link water-soluble polymers having

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charged side chains to form a gel. However, the preferred polymers of Hanes et al are not water soluble polymers having charged side chains. Therefore, one of ordinary skill in the art would not have found it obvious to modify Hanes et al based on the teachings of Cohen et al. Specifically, poly(lactic acid) and poly(glycolic acid) are not charged polymers, and one of ordinary skill in the art would recognize that the addition of calcium would not result in the cross-linked formation of a gel as taught by Cohen et al. Therefore, it would not have been obvious to one of ordinary skill in the art to add calcium to the particles of Hanes et al.

It would also not have been obvious to one of ordinary skill in the art to substitute a water-soluble polymer having charged side chains for the preferred polymers of Hanes et al and then to add calcium to form a gel. In the first place, there is no motivation for making the polymer substitution. Secondly, to make the polymer substitution and to form a cross-linked gel would go against the teachings of Hanes et al. Hanes et al teaches the desirability of aerodynamically light particles for aerosol delivery. If the Hanes et al composition was formed into a cross-linked gel, as taught by Cohen et al, the resulting composition would not be able to be formed into discrete particles and particularly not into discrete particles of the sizes described by Hanes et al and of the sizes claimed in claim 39. Note that in column 3 lines 32-35 of Cohen et al, Cohen et al does not list inhalation as a potential mode of delivery. Note, too, that Hanes et al and Cohen et al share an inventor, and the inventors of Hanes et al clearly did not find it desirable to incorporate the teachings of Cohen et al. In addition, the cross-linked gel of Cohen et al could not be formulated in the manners described by Hanes et al. For example, the resulting cross-linked gel could not be spray dried, as taught in Hanes et al Example 2. For at least these reasons, it would not have been obvious to one of ordinary skill in the art to modify Hanes et al with the teachings of Cohen et al, and even if Hanes et al were modified as proposed, it would not result in the invention set forth in Applicant's claim 39.

Claim 39 is also not rendered unpatentable by Hanes et al, Cohen et al, and Yen. Yen does not make up for the deficiencies of Hanes et al and Cohen et al in teaching the invention set forth in claim 39. Accordingly, Hanes et al, Cohen et al and Yen do not render claim 39 unpatentable.

Claims 4-15, 18-23, 52, 53, and 55 depend from claim 39 and are not rendered unpatentable by Hanes et al, Cohen et al, and Yen for at least the same reasons as the claim from which they depend. In addition, the claims recite further distinguishing features. For example, claim 4 recites that the microstructures are porous. Claim 12 recites that the microstructures are

hollow and porous. Claim 15 recites that the mean geometric diameter is less than about 5 microns.

Independent claim 40 is also not rendered unpatentable by Hanes et al, Cohen et al, and Yen. Claim 40 is to an inhaleable powder composition comprising a plurality of particulate microstructures, said microstructures comprising a structural matrix comprising calcium, an active agent and a phospholipid. As discussed above, Hanes et al does not disclose the incorporation of calcium in a microstructure, and Cohen et al and Yen do not teach the addition of calcium in a way that one of ordinary skill in the art would find it obvious to add calcium to the Hanes et al particles. Therefore, claim 40 and claims 41-51, 54, and 56 depending therefrom are patentable over the cited references.

Claim Amendments

Claims 4-15, 18-23, 39-47, and 49-51 have been amended. Except for claim 43, as discussed above, all of these amendments have been made to improve the form of the claims and/or to remove unnecessary limitations and have not been made for reasons related to patentability.

New Claims

Claims 52-56 have been added to define other aspects of Applicant's invention.

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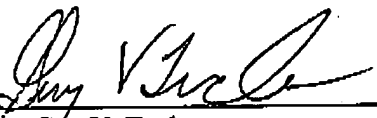
Conclusion

The claims are allowable for the reasons given above. Thus, the Examiner is respectfully requested to reconsider the present rejections and allow the presently pending claims. Should the Examiner have any questions, the Examiner is requested to call the undersigned at the number given below.

Respectfully submitted,

NEKTAR THERAPEUTICS
(formerly INHALE THERAPEUTIC
SYSTEMS)

Dated: 21 JAN 04

By: 
Guy V. Tucker
Reg. No. 45,302

Please send all correspondence to:
Guy Tucker
Nektar Therapeutics
(formerly Inhale Therapeutic Systems, Inc.)
150 Industrial Road
San Carlos, CA 94070
Phone: (650) 620-5501
Fax: (650) 631-3125

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